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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/117,380	01/27/1999	MATITYAHU FRIDKIN	FRIDKIN=1	3626

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EXAMINER

HUTSON, RICHARD G

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 12/04/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/117,380

Applicant(s)

FRIDKIN ET AL.

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-9, 12, 13 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 2-9, 12, 13 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- ☐ Interview Summary (PTO-413) Paper No(s). _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Applicants amendment deleting claims 14-24, amending claims 2, 3, 5, 8, 9 and 12 and adding new claim 25, Paper No. 28, 2/9/2000, is acknowledged.

Claims 2-9, 12, 13 and 25 are still at issue and are present for examination.

Applicants' arguments filed on 2/9/2000, Paper No. 28, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Objections

Claim 25 is objected to because of the following informalities: Claim 25 recites "...the proviso that the residue at 96 is not Ile all at the same time;...". It is suggested that a comma be inserted after Ile, such as "...the proviso that the residue at 96 is not Ile, all at the same time;..."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-9, 12, 13 and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants newly added claim 25 (claims 2, 3, 4, 5, 6, 7, 8, 9, 12 and 13 dependent from) is rejected as containing new matter because the recitation "...with the proviso that the residue at 89 is not Leu, the proviso that the residue at 90 is not Glu, the proviso that the residue at 91 is not Ala, the proviso that the residue at 92 is not Ile, the proviso that the residue at 94 is not Val, the proviso that the residue at 95 is not Ser, the proviso that the residue at 96 is not Ile all at the same time;...", is not supported by the original disclosure.

Applicants comments regarding the previous interview and discussion of applicants claims with respect to 112 issues are acknowledged, however applicant is reminded that the present claims are not identical to those previously discussed and further, as was previously stated to applicant's representative, the examiner previously provided a cursory review, and a thorough examination and/or search of the proposed claims was not completed. This was pointed out to applicants representative in the previous interview summary.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 3 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Barr et al. (U.S. Patent No: 4,732,973, issued 3/22/1998).

The original rejection is stated in the previous office action, Paper No. 19, 8/21/2001, as it applied to previous claims 1-4 and 9 and in Paper No. 26, 7/8/2002, as it applied to claims 15-18 and 22. Applicants have cancelled claims 1, 15-18 and 22 and amended claims 2-4 and 9, to depend from newly added claim 25.

As previously discussed, Barr et al. teach a proteinaceous composition to inhibit naturally occurring serine proteases, particularly an amino acid sequence analogous to human α 1-antitrypsin, which is modified at the active site while maintaining protease inhibition. Barr et al. specifically claim an analog of human alpha-1-antitrypsin wherein the amino acid corresponding to the methionine at position 358 is changed to a valine, or alanine. These variants comprises the sequences "...leu₃₅₃-glu-ala-ile-pro-val-ser-ile₃₆₀..." and "...leu₃₅₃-glu-ala-ile-pro-ala-ser-ile₃₆₀..." which anticipates claims 25, 2 and 3. Barr et al. further teach that said peptides comprise the residues leucine, and isoleucine at those sites designated as hydrophobic residues and the N-terminal extension of the taught peptide.

In response to the previous office action in which claims 15-18 and 22 were rejected by Barr et al., applicants have canceled claims 15-18 and 22, added new claim 25 and amended claims 2-9, 12 and 13 to depend from claim 25.

Claim 25 as presented is anticipated by Barr et al. on the basis that the claim incorporates the proviso that the claimed peptide can not consist of the core sequence "...leu-glu-ala-ile-pro-val-ser-ile...". Upon closer examination, Barr et al. teaches an additional peptide comprising the core sequence "...leu³⁵³-glu-ala-ile-pro-^{354 355 356 357 358 359}ala-ser-³⁶⁰ile³⁶⁰..." (See claim 2 of Barr et al.). Thus claims 25, 2 and 3 are anticipated by Barr et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barr et al. (U.S. Patent No: 4,732,973, issued 3/22/1998).

As discussed above, Barr et al. teach a proteinaceous composition to inhibit naturally occurring serine proteases comprising an analog of human alpha-1-antitrypsin wherein the variant comprises the sequence "...leu³⁵³-glu-ala-ile-pro-ala-ser-ile³⁶⁰..." Further, Barr et al. teaches that this variant inhibits human elastase activity (See columns 13-15) and that failure to inhibit elastase in the lungs can result in pulmonary emphysema or acute respiratory distress syndrome. Barr et al. further teach the use of said proteinaceous compositions for a number of therapeutic purposes. One of ordinary

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skill in the art would be motivated to create a pharmaceutical composition comprising a variant of human alpha-1-antitrypsin wherein the variant comprises the sequence "...leu₃₅₃-glu-ala-ile-pro-ala-ser-ile₃₆₀..." as taught by Barr et al. and using such a pharmaceutical composition as an anti-inflammatory medication and a means of protecting a host from elastase related damage to the lungs associated with pulmonary emphysema or acute respiratory distress syndrome. The reasonable expectation of success comes from the results of Barr et al. and the high degree of knowledge in the art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Richard Hutson', with a long horizontal line extending to the right.

Richard Hutson, Ph.D.
Patent Examiner
Art Unit 1652
December 2, 2002